Integrated Risk Information System (IRIS)

History

IRIS is a database containing information about a chemical's principle toxic effect and a concentration or dose at which the chemical will not likely cause this effect, even in sensitive humans. For chemicals where cancer is the principle toxic effect, this concentration or dose is associated with a very low risk of cancer (usually one chance in a million people). For chemicals that have another principle toxic effect (like liver toxicity), this concentration or dose is considered safe. Collectively, these concentrations or doses are referred to as **risk values**.

The determination of the principle toxic effect is referred to as **hazard identification** (although other effects at higher concentrations or doses are also described). The determination of these risk values is referred to as **dose response assessment**. Importantly, all EPA offices use these risk values along with a particular chemical's **exposure assessment** for rulemaking. These three processes, hazard identification, dose response assessment and exposure assessment are used to characterize a chemical's potential risk to humans and are all a part of **risk assessment** as described by EPA in many guidance documents based on the work of the National Academy of Sciences. A similar risk assessment process is also used for protecting the ecosystem.

Up until 1995, IRIS contained risk values on over 500 chemicals and was considered to be the place where all important EPA risk values were placed. Two senior EPA technical groups met monthly to review all risk values before placing them on IRIS. Risk values on IRIS were considered to be THE EPA value for the particular chemical, and were to be used by all staff until more appropriate values were developed.

After 1995 the senior agency work groups disbanded and each office returned to its individual approach. IRIS slowly became out of date. Importantly, senior agency scientists from around EPA did not always have the opportunity to review each other's work. As a result, not all information on IRIS is the fruit of EPA's best scientists. Nor is IRIS considered to be EPA's database anymore, even among many outside groups. This is because not all risk values routinely developed by EPA offices are placed on IRIS.

Political pressures

IRIS provides some very important and credible information, but this information is often side-by-side information that is more than 20 years out of date. Moreover, some newer IRIS information reflects the lack of senior scientist oversight from multiple EPA perspectives, and thus may not be EPA's best risk value. Some individuals and groups, who are generally not adept in this area of science, will pressure EPA to maintain IRIS. These groups generally do not understand the current problems with the system. Other individuals and groups, who generally understand the problems with IRIS, will pressure EPA to scrap it. This is due to their frustration of getting scientifically credible information considered in the development of risk values.

Fortunately, a third option exists. Briefly, return the placement of information on IRIS into the hands of a senior EPA technical group.

One way forward

A senior EPA group, composed on EPA's best scientists in the area of risk value development, could be established within 2 weeks. This group would have 10 toxicologists and epidemiologists, each of which would have a minimum of 20 years of experience in developing risk values. The group could be organized out of the Office of the Administrator initially, and would meet monthly, or more often if needed, to review risk values and underlying methods. Risk values to be reviewed by this senior EPA group would come from the same EPA offices that now develop this information: OW, NCEA, OPP, and OPPT, although the occasional risk value developed by another EPA group would be welcome.

One advantage of this approach would be that risk value development would be maintained in individual EPA offices that could otherwise maintain their own processes for document development and peer review. The actual loading of IRIS values could also be maintained in NCEA, or moved to another office, if this is considered more appropriate. Importantly, the senior EPA group would have the final say on whether a risk value is loaded onto IRIS. This decision would be independent of individual EPA offices.

Another advantage of this option is that monthly meetings of this senior EPA group could replace other, generally more time consuming, intra-EPA reviews of risk value information, especially when such reviews rely on writing memos. In contrast to writing memos, monthly face-to-face meetings of this senior EPA group could resolve issues or disagreements in a much shorter time frame. For example, most risk values were cleared by the former senior agency work groups in two meetings.

This approach would cost about 4 FTEs yearly and ~20K in travel monies for several of the senior EPA experts. This FTE cost is determined by about 0.2 FTE for each of the 10 senior EPA experts, and another 2 FTEs to organize the monthly meetings. Also, individual offices would need to prepare information for the monthly review meetings for the senior EPA group, and depending on whether or not this is already done, this preparation might necessitate additional work.

Time Frame

- November 2017: A senior EPA group is formed.
- December 2017: Files for available risk values are prepared for work group review.
- January 2018: A 2-day work group review meeting is held; ~4 files are loaded onto IRIS.
- 2018: Monthly meetings clear approximately 4 to 8 files per month.
- September 2018: IRIS is again seen as EPA's risk value system.
- September 2020: IRIS has partnered with US State agencies to share work.
- September 2022: IRIS has partnered with world health organizations to share work.